UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,665	08/13/2001	Neil H. Bander	266/187	9976

26161 7590 08/26/2003

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER
NICKOL, GARY B

ART UNIT	PAPER NUMBER
1642	14

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/929,665	BANDER, NEIL H.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *144-183* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *144-183* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Preliminary Amendment filed 3-22-02 (Paper No. 11) is acknowledged and has been entered.

Claims 83-143 were cancelled.

Claims 144-183 were added and are currently pending.

Specification

The specification is objected to on page 42, line 3 for reciting "nucleotide" since the sentence is in reference to an amino acid sequence.

The specification is objected to on page 43, line 33 for reciting "nucleotide" since the sentence is in reference to an amino acid sequence.

The specification is objected to on page 44, line 33 for reciting "nucleotide" since the sentence is in reference to an amino acid sequence.

Claim Objections

Claims 145, 147, 149, 151, 153, 155 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The objected claims all depend from Claim 144 or 150, Markush-type claims drawn to *discrete* antigen binding portions. However, the objected claims are broader in scope than Claims 144 or 150 because they include different antigen binding portions than those claimed in Claim 144 or 150. For example, Claim 145 includes an antigen binding portion of an amino acid sequence of

the variable heavy chain produced by hybridoma having ATCC deposit no. HB-12126 *and* an antigen binding portion of an amino acid sequence of SEQ ID NO:19 (variable light chain) *or* an amino acid sequence of the variable light chain produced by the hybridoma having ATCC deposit no. HB-12126. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 145 and 151 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are so unclear that no meaningful interpretation can be made as to what exactly the antigen binding portions comprise. For example, Claim 145 includes an antigen binding portion of an amino acid sequence of the variable heavy chain produced by hybridoma having ATCC deposit no. HB-12126 *and* an antigen binding portion of an amino acid sequence of SEQ ID NO:19 (variable light chain) *or* an amino acid sequence of the variable light chain produced by the hybridoma having ATCC deposit no. HB-12126. Are these portions conjugated to one another? Are they separate? What exactly is meant by including the term "and" ? What is meant by including the term "or" ? Hence, the metes and bounds of the claims cannot be determined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 145, 147, 149, 151, 153, 155 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regards to Claims 145, 147, 149, 151, 153, 155, the specification does not appear to have support for antigen binding portions conjugated to one another. For example, Claim 147 is drawn to antibody or antigen binding portion thereof that comprises an antigen binding portion of an amino acid sequence from SEQ ID NO:8 *and* an antigen binding portion of an amino acid sequence from SEQ ID NO:19. However, the specification only supports those antigen binding portions selected from the group consisting of SEQ ID NO:8, SEQ ID NO:19, an amino acid sequence of the variable heavy chain produced by the hybridoma having ATCC deposit No. HB-12126, and an amino acid sequence of the variable light chain produced by the hybridoma having ATCC deposit No. HB-12126.

Although, the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP § 714.02 and § 2163.06 ("Applicant should specifically point out the support for any amendments made to the disclosure.")

Claims 144-145, 148-151, and 154-183 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure with regards to the claimed hybridomas and monoclonal antibodies. Without a publicly available deposit, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Thus, applicants' referral to the four hybridoma deposits on page 30 of the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. Although applicants state that the deposits were made under the provisions of the Budapest Treaty, applicants do not state that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if the depository cannot dispense viable samples. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 144-160, 172-173, 178-183 are rejected under 35 U.S.C. 102(b) as being anticipated by EP125023-A (Cabilly *et al.*, November 1984)

The claims are broadly drawn to isolated antibodies or antigen binding portions thereof that comprise antigen binding portions of certain amino acid sequences including those sequences present in SEQ ID NO:8, SEQ ID NO:19, sequences present in the variable heavy chain produced by the hybridoma HB-12126, and the variable light chain produced by the hybridoma HB-12126. Thus, for the purpose of comparing the claims to the prior art, the claims are interpreted as comprising *any* antigen binding portion (of any length) that contains *any* one amino acid sequence of the aforementioned sequences.

Cabilly *et al.* teach an isolated antibody or antigen binding portion thereof comprising an antigen binding portion of an amino acid sequence selected from the group consisting of SEQ ID NO:19 (variable light chain) which further encompasses antigen binding portions of an amino acid sequence of the variable light chain produced by the hybridoma having ATCC deposit number HB-12126. (See attached sequence comparison). The art further reads on an isolated antibody or antigen binding portion thereof which comprises an antigen binding portion of an amino acid sequence selected from the group consisting of SEQ ID NO:8 (variable heavy chain) and SEQ ID NO:19 (variable light chain) (Claims 146-149) because the referenced antibody comprises amino acid sequence portions of both SEQ ID NO:8 or SEQ ID NO:19. The prior art further reads on an isolated antibody or antigen binding portion thereof comprising an antigen binding portion of an amino acid sequence *encoded* by SEQ ID NO:17 (variable light chain) or a nucleic acid which encodes the variable light chain produced by the hybridoma having ATCC deposit no. HB-12126 since the prior art protein encompasses nucleic acids which encode such antigen binding portions. The art further teaches that said antibodies are monoclonal or polyclonal (page 3) and further teaches Fab fragments (page 9, 13), antibody complexes

comprising therapeutic drugs (top of page 4), labels with radioisotopes or with enzymes (page 3), isolated lymphocytic cells producing said antibodies or antigen binding portions (page 2). And, although the prior art does not characterize the antigen-binding portion as those which are internalized with the prostate specific membrane antigen, the claims are drawn to the product *per se*, and inherently would display such a feature. Furthermore, with regards to the kits, the claims only read on the product *per se* and the wording of a kit does not have patentable weight when comparing the claims to the prior art.

Claims 144-173, 178-183 are further rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/07493 (Better *et al.*, May 1991).

Better *et al.* teach an isolated antibody or antigen binding portion thereof comprising an antigen binding portion of an amino acid sequence selected from the group consisting of SEQ ID NO:8 (variable heavy chain) which further encompasses antigen binding portions of an amino acid sequence of the variable heavy chain produced by the hybridoma having ATCC deposit number HB-12126. (See attached sequence comparison). The art further reads on an isolated antibody or antigen binding portion thereof which comprises an antigen binding portion of an amino acid sequence selected from the group consisting of SEQ ID NO:8 (variable heavy chain) and SEQ ID NO:19 (variable light chain) (Claims 146-149) because the referenced antibody comprises amino acid sequence portions of both SEQ ID NO:8 or SEQ ID NO:19. The prior art further reads on an isolated antibody or antigen binding portion thereof comprising an antigen binding portion of an amino acid sequence *encoded* by SEQ ID NO:6 (variable heavy chain) or a nucleic acid which encodes the variable heavy chain produced by the hybridoma having ATCC

deposit no. HB-12126 since the prior art protein encompasses nucleic acids which encode such antigen binding portions. The art further teaches (page 3) antibodies having monovalent specificity and monoclonal antibodies from isolated lymphocytic cells (page 8), Fab fragments (page 3), antibody complexes comprising therapeutic drugs, cytotoxic proteins, plant toxins, and bacterial toxins, radionuclides (page 14), labels with radioisotopes or with enzymes (page 30,33,66), And, although the prior art does not characterize the antigen-binding portion as those which are internalized with the prostate specific membrane antigen, the claims are drawn to the product *per se*, and inherently would display such a feature. Furthermore, with regards to the kits, the claims only read on the product *per se* and the wording of a kit does not have patentable weight when comparing the claims to the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 144-158, 172-173, 178-183 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22, of U.S. Patent No. 6,107,090. Although the conflicting claims are not identical, they are not patentably distinct

from each other because the claims of the pending application include the same antibody species as those claimed in the patented claims. For example, claim 144 of the pending application is drawn to an isolated antibody or antigen binding portion thereof, comprising an antigen binding portion of an amino acid sequence of SEQ ID NO:8. SEQ ID NO:8, according to the specification (page 42), corresponds to the heavy chain variable region of the J591 monoclonal antibody. Thus, the claims broadly include the monoclonal antibody referred to as J591 claimed in Claim 4 of the '090 patent.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
August 21, 2003